510(k) Summary

1. Contact Information

Submitter: NovoSci, Inc.
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

405.826.0713 Phone
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Contact Person: David Makanani

Date Prepared: October 15, 2007

2. Device Names

Trade: ***NovoFlo*™ Catheter LT** Dual Lumen Long Term Hemodialysis Catheter

Common Name: Hemodialysis Long Term Catheter

Classification Name: 78 MSD – Catheter, Hemodialysis, Implanted
21 CFR 876.5540

3. Predicate Device

Medcomp Hemo-Flow Catheter, K994105
Medcomp Hemo-Flow Catheter, K030502

4. Description of Device

The ***NovoFlo*™ Catheter LT** Dual Lumen Long Term Hemodialysis Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.

The Hemodialysis Catheter can be connected to an extracorporeal tubing system via a connecting tube equipped with a Luer-Lock connector.

The proximal lumen (red clamp) provides "arterial" blood outflow from the patient, the distal lumen (blue clamp) provides "venous" blood return to the patient. Important information such as priming volume and catheter length is printed on both sides of the clamp.

The catheter comes in a variety of sizes and lengths with straight or curved extensions.

5. Indications for Use

- The ***NovoFlo*™ Catheter LT** Dual Lumen Long Term Hemodialysis Catheters are indicated for use in attaining Long Term vascular access for hemodialysis and apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein as required.
- Catheters greater than 40cm in length are intended for femoral vein insertion.

6. Comparison to Predicate Device

The ***NovoFlo***™ **Catheter LT** Dual Lumen Long Term Hemodialysis Catheter is substantially equivalent to the Medcomp Hemo-Flow Long Term Catheter.

A close examination of specifications reveals that there are no major differences in design, materials, performance, biocompatibility, safety and product effectiveness.

7. Non-clinical Performance Tests:

Engineering studies were performed to FDA's "Guidance on Premarket Notification 510(k) Submissions for Short Term and Long Term Intravascular Catheters", and "Coronary and Cerebrovascular Guidewire Guidance", ISO 10555 – International standard for "Sterile, Single-Use, Intravascular Catheters, ISO 10993 – International standard for "Biological Evaluation of Medical Devices", and additional test requirements for hemodialysis catheters.

8. Conclusion

The ***NovoFlo***™ **Catheter LT** Dual Lumen Long Term Hemodialysis Catheter was demonstrated to be substantially equivalent to the predicate device based on its design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Makanani
Vice-President
NovoSci, Inc.
2828 N. Crescent Ridge Drive
WOODLANDS TX 77281

OCT 3 0 2007

Re: K072499
Trade/Device Name: ***NovoFlo***™ Catheter LT Dual Lumen Long Term Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: August 31, 2007
Received: September 5, 2007

Dear Mr. Makanani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072499

Device Name: *NovoFlo*™ Catheter LT Dual Lumen Long Term Hemodialysis Catheter

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072499